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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,623	10/10/2003	Katsuyuki Inoo	01371/2/US	1832

7590 12/05/2006

PHARMACIA CORPORATION

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT PAPER NUMBER

1618

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/683,623	Applicant(s) INOO ET AL.	
	Examiner Micah-Paul Young	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/7/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Acknowledgment of Papers Received: Information Disclosure Statement dated 6/7/04.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 1-4,6-9 and 16-18 rejected under 35 U.S.C. 102(e) as being anticipated by Xiong et al (USPN 6,896,898 hereafter '898). The claims are drawn to a transdermal patch comprising an adhesive matrix comprising a COX-2 inhibitor, a flexible backing layer and a solvent system. The claims also recite a method of using said patch.

2. The '898 patent discloses a transdermal patch comprising pain and inflammation relievers (abstract). Agents useful for the relieving of pain and inflammation include celecoxib a well-known COX-2 inhibitor (col. 3, lin. 27; Formula V-16). The adhesive matrix is a reservoir comprising a solvent system comprising N-methyl-2-pyrrolidone (col. 10, lin. 24), skin

Art Unit: 1618

permeation enhancers/tackifiers resins such as glycerol monooleate and sorbitan monooleate (col. 9, lin. 66-col. 10, lin. 5), styrene-isoprene-styrene block copolymers and liquid rubbers (col. 15, lin. 7-16). The matrix further includes crystallization inhibitors/thickeners/softening agents (col. 13, lin. 58-67), humectants (col. 13, lin. 36-47), antioxidants (col. 12, lin. 60-65), and preservatives (example VI). These formulations are applied to backing material that can be flexible (col. 15, lin. 53-60). The patches also have a peelable release liner (col. 15, lin. 60-64). The patches are applied to the skin (col. 16, lin. 13-24). The patches are useful in treating pain and inflammation; conditions associated with COX-2 mediated disorders (col. 1, lin. 13-16). These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1618

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Xiong et al (USPN 6,896,898 hereafter '898) in view of Lu et al (US 2003/0161867 hereafter '867). The claims are drawn to a transdermal patch comprising an adhesive matrix comprising a COX-2 inhibitor, a flexible backing layer and a solvent system. The claims also recite a method of using said patch.

6. As discussed above the '898 patent discloses a transdermal patch comprising an adhesive layer a reservoir layer, a solvent system and COX-2 inhibitor. The reference is silent however to the specific COX-2 inhibitor recited in the claims. However COX-2 inhibitors of the claims are seen as equivalents in the art as seen in the '867 patent.

7. The '867 patent discloses a dermal transdermal formulation comprising valdecoxib (Table 1) permeation enhancers [0086], solvents, surfactants and thickening agents [0099]. Since celecoxib and valdecoxib are relatively interchangeable in the art, it would be obvious to one of ordinary skill to include the valdecoxib described in the dermal formulation of the '867 into the transdermal patch of the '898 patent.

Art Unit: 1618

8. Regarding the specific concentrations of the components, it is the position of the Examiner that these limitations represent an optimization of ranges that can be determined through routine experimentation in the art. The general conditions of the art have been met by the disclosures of the '898 patent. Formulations include preservatives, thickeners, permeation enhancers and active agents all within the ranges recited in the claims (examples). Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).
9. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).
10. With these aspects in mind it would have been obvious to one of ordinary skill in the art to include the valdecoxib of the '867 patent into the patch of the '898 patent in order to impart specific COX-2 inhibiting properties on the patch. One of ordinary skill in the art would have been motivated to combine the teachings with an expected result of a transdermal patch capable of treating pain and inflammation.

Art Unit: 1618

Correspondence


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


MP Young

Micah-Paul Young
Examiner
Art Unit 1618


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER